DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 19, 2014

Cook Ireland Ltd
Nora O'Connor
Regulatory Affairs Specialist
O'halloran Road
National Technology Park
Limerick
Ireland

Re: K142688
Trade/Device Name: Echotip Procore® Hd Ultrasound Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: FCG
Dated: September 18, 2014
Received: September 22, 2014

Dear Nora O'Connor,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K142688

Device Name: EchoTip Procore® HD Ultrasound Biopsy Needle

Indications for Use:

This device is used with an ultrasound endoscope for fine needle biopsy, (FNB), of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.

Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D) ___✓___		(21 CFR 801 Subpart C) _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

I. SUBMITTER

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Date Prepared: October 31, 2014

II. DEVICE

Trade Name of Device: EchoTip Procore® HD Ultrasound Biopsy Needle.
The model number is ECHO-HD-(3)-XX-C where XX denotes the needle gauge size.

Common or Usual Name: Endoscopic Ultrasound Needle (Biopsy Needle Kit)

Classification Name: Gastroenterology-urology biopsy instrument (21 CFR 876.1075)

Regulatory Class: II

Product Code: FCG

III. PREDICATE DEVICE

Cook Endoscopic Ultrasound Needle, K083330.
Biopsy Sciences, LLC Maxi-Cell Biopsy Needle, K021847

IV. DEVICE DESCRIPTION

The EchoTip Procore® HD Ultrasound Biopsy Needle is used in conjunction with an ultrasound endoscope and is available with needle gauge sizes of 19, 20, 22 and 25 ga. The device comprises of a needle assembly and a syringe. The needle assembly consists of the needle cannula, stylet, sheath and handle. The stainless steel needle cannula has a dimpling pattern on the distal end to allow visualization of the needle tip under endoscopic ultrasound. The needle cannula has a bevelled tip design and a notch. The purpose of the needle cannula is for puncturing/biopsy of the target site. The preloaded nitinol stylet is withdrawn from the needle for biopsy. Some variants have a stylet that coils when not in the needle. The sheath covers the needle when it's not in use. The device handle allows for needle and sheath length adjustment. The syringe can aid in tissue aspiration. The device is supplied sterile and is intended for single use. The device is for Rx used only.

V. INDICATIONS FOR USE

This device is used with an ultrasound endoscope for fine needle biopsy, (FNB), of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.

VI. COMPARISON OF TECHNOLOGICAL CHARACETERISTICS WITH A PREDICTE DEVICE

The modified device is substantially equivalent to the currently marketed device, the Cook Endoscopic Ultrasound Needle, as cleared by K083330. Both devices operate in the same manner to obtain a tissue biopsy using an ultrasound endoscope.

The modified device is substantially equivalent to the currently marketed device, Biopsy Sciences, LLC Maxi-Cell Biopsy Needle, as cleared by K021847. Both the modified and predicate device operate in a similar manner to obtain a sample.

At a high level, the modified device is identical to/ within the range of the Cook Endoscopic Ultrasound Needle predicate device with respect to the following:

- Needle gauge range and material,
- Needle length adjustment range and sheath extension adjustment range,
- Stylet diameter range and material,
- Stylet tip options,
- Compatibility with an ultrasound endoscope,
- Use with a syringe,
- Mechanism/principle of operation (manual, sampling using cutting and aspiration),
- Method of needle and sheath adjustment (handle),
- For single use, and
- Sterility (using EO).

The following technological differences exist between the modified device and the Cook Endoscopic Ultrasound Needle predicate device:

- Needle cannula - addition of notch,
- Stylet - shape upon removal (coiled), stylet distal tip location and stylet cap,
- Sheath - material (addition of a covering, change in colour), outer diameter change,
- Handle - colour change (non-patient contacting).

The modified device is identical to/ within the range of the Biopsy Sciences, LLC Maxi-Cell Biopsy Needle with respect to the following:

- Needle material ,
- Presence of a notch on the needle,
- Used with a syringe,
- Mechanism/principle of operation (manual, sampling using cutting and aspiration),
- For single use, and
- Sterility (using EO).

The EchoTip Procore® HD Ultrasound Biopsy Needle has the following differences to the features of the Biopsy Sciences, LLC Maxi-Cell biopsy needle:

- Needle gauge range,
- Stylet material, shape upon removal,
- The addition of a sheath, and
- The handle type.

VII. PERFORMANCE DATA

The biocompatibility evaluation for EchoTip Procore® HD Ultrasound Biopsy Needle was conducted in accordance with *ISO 10993-1*: *2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process"* and FDA's biocompatibility guidance, *G95-1 Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (May 1, 1995).* The following tests were completed: Cytotoxicity, Sensitization and Intracutaneous reactivity.

The device specific guidance document was consulted in preparing this premarket submission, *Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology.* Performance testing such as visual inspection, dimensional inspection, simulated use, stylet removal force testing and joint strength testing were performed as per Cook Ireland's design control system.

VIII. CONCLUSIONS

Non-clinical testing carried out on the device supports the substantial equivalence of the EchoTip Procore® HD Ultrasound Biopsy Needle to the predicate devices and provides a reasonable assurance of safety and effectiveness.